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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,783	01/25/2002	Anthony C. Forster	AFOR-P01-001	9343

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,783	FORSTER ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *18 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-17 and 19, drawn to a cell-free translation system for generating a peptide product or a peptidomimetic product, a kit comprising the translation system, and a method for generating a peptide product or a peptidomimetic product using the system, classified in class 435, subclasses 68.1 and 69.1, and class 536, subclass 23.1.

II. Claim 18, drawn to a peptide or peptidomimetic, classified in class 530, subclass 350.

III. Claims 20-22, drawn to a method of conducting a drug discovery business using the peptide or peptidomimetic, classified in class 530, subclass 350, and class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

The translation system of Invention I is related to the product of Invention II by translating the mRNA to produce the peptide of Invention I. However, they are distinct invention because they are physically and functionally distinct chemical entities, and the peptide can be made by another and materially different process such as solid phase peptide synthesis.

The process of Invention I and the product of Invention II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and

materially different process (MPEP § 806.05(f)). In the instant case the peptide can be produced by another and materially different process such as solid phase peptide synthesis.

The product of Invention I is distinct from the method of Invention III because the product of Invention I can be neither made nor used by the method of Invention III.

The methods of Inventions I and III are patentably distinct each from the other because they have different method steps, utilize different materials and producing different outcomes.

The product of Invention II and the method of Invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention II can be used as a reagent for in vitro assay or for production of antibodies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and different classification, and because Inventions I-III require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Matthew Vincent on February 11, 2004, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-17 and 19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18 and 20-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Informalities

The disclosure is objected to because of the following informalities:

3. The specification recites amino acid and nucleotide sequences (e.g., page 12, line 33; page 22, line 30), however, the sequence identifier "SEQ ID NO:" is not indicated. Applicant must comply with the requirements of sequence rules (37 CFR 1.821-1.825) to include all the sequences in the sequence listing and to identify each sequence with a "SEQ ID NO:". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 4, 5, 7-17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 2, 4 and 5 are indefinite because of the use of the term "substantially free". The term "substantially free" renders the claim indefinite, it is not clear whether the preparation contains any amount of the translation factors EF-P, W, W2 or rescue, or not at all as to "substantially free". Claims 4 and 5 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend. Claims 4 and 5 are also indefinite because the claims cite the translation system for generating a peptidomimetic product, which does not conform the limitation of claim 2, which is the translation system for generating a peptide product. Claim 5 is also indefinite as to "alkyne derivative" or "radioisotope derivative", it is not clear what the derivative is, and how different the derivative is as compared to the parent compound. Use of "alkyne compound" or "radioisotope compound" is suggested.

6. Claim 7 recites the limitation "said inactive tRNA species" in lines 7-8. There is insufficient antecedent basis for this limitation in the claim. Claims 8 and 10 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

7. Claims 9 and 10 are indefinite as to what these instructions are, and what the kit is used for.

8. Claims 11-17 and 19 are indefinite because the claim lacks an essential step in the method for generating a peptide or peptidomimetic. The missing step is the translation step. Claims 11 and 19 are also indefinite because of the use of the term "and/or". The

term "and/or" renders the claim indefinite, it is unclear whether the limitation after "and/or" is included or not, and if included is to be read as an alternative "or" or the conjunctive "and". Claims 12-17 and 19 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by Stada *et al.* (Nucleic Acids Res. 22, 1394-1399 (1994)).

Stada *et al.* teach an in vitro peptide synthesis system that contains a reaction mixture of 70 S 'tight couple' ribosomes from E. coli, an mRNA by T7-transcription from a synthetic DNA, a formylated or diazirine-derivatized Met-tRNA^{fMet} and translation factors such as IF-1, IF-2 and IF-3 in HEPES-KOH, pH 7.5 buffer, which are incubated at 37 °C for 10 min. Reaction mixtures of each of the charged tRNA species such as a derivatized Lys-tRNA^{Lys} required for the particular peptide (e.g., Met-Lys-Phe-Glu), EF-Tu, EF-G in HEPES-KOH, pH 7.5 buffer are prepared, after 2 min at 37 °C, each mixture is added to the initial reaction mixture and incubated for a further 15 min at 37 °C to synthesize the peptide (page 1395, left column; claims 1-7), where the reaction mixtures do not contain the translation factors EF-P, W, W2 or rescue, and the use of

formylated or diazirine-derivatized Met-tRNA^{fMet} and derivatized Lys-tRNA^{Lys} in the system meet the criteria of claims 2, 4, 5 and 7.

10. Claims 1, 3, 6, 7, 11 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by Ganoza *et al.* (Proc. Natl. Acad. Sci. USA 82, 1648-1652 (1985)).

Ganoza *et al.* teach in vitro translation system using purified components that include ribosomes, an mRNA of MS2 or f2RNA or f2am3 RNA, translation factors such as IF-1, IF-2, IF-3, EF-Tu, EF-Ts, EF-T, EF-G, release factors such as rescue protein, EF-P and W, f[^{35}S]Met-tRNA^{fMet} and other unlabeled aminoacyl-tRNAs in Tris, pH 7.4 buffer for one step transfer reaction to synthesize a peptide such as fMet-Ala-Ser-AspNH_2-Phe-Thr, and the reaction mixture are incubated for 30 min at 35 °C (page 1649, left column; claims 1, 3, 6, 7, 11 and 12). The f2am3-directed synthesis products labeled with f[^{35}S]Met-tRNA^{fMet} and each unlabeled aminoacyl-tRNAs are shown by electrophoretic analysis indicates W stimulates the synthesis of the hexapeptide (Fig. 4; page 1650). The use of f[^{35}S]Met-tRNA^{fMet} in the system meets the criteria of claim 7.

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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March 19, 2004

ROBERT A. WAX
PRIMARY EXAMINER